REMARKS/ARGUMENTS

Reconsideration of this application and entry of this Amendment are solicited. It is proposed to revise claims 144 and 145 to reduce issues and advance prosecution of this application.

Claim 144, from which all of the remaining claims depend, is above amended in order to more particularly point out and distinctly claim that which applicants regard as their invention to specify the pore size of the mesoporous silicon is between 20 and 500 Å (2-5 nm) as stated in the description at page 5, lines 4-6. Claim 145 is amended for purposes of clarity.

The sole issue presented is the patentability of these claims over the disclosures of WO 97/06101 to Canham et al.

Before discussing the rejection in detail, it is important that the terms used are correctly understood. A clear distinction must be made between microporous silicon, which is described on page 14, lines 1 to 10 of WO '101, with mesoporous silicon. **Micro**porous silicon has a pore size less than 20 Å, whereas **meso**porous silicon has a pore size between 20 and 500 Å as applicants' claims now specifically state (see page 3, lines 23 to 28 of WO '101). WO '101 does describe microporous silicon that has been impregnated with calcium chloride, but it does not describe mesoporous resorbable silicon that has a drug located in its pores.

Pore size is critical to resorbability, hence applicants propose to include it in claim 144, the only independent claim. Only mesoporous silicon is described, in WO '101, as "resorbable". However, a small amount of dissolution of silicon may be an important factor in the bioactivity of certain forms of porous silicon (page 14, lines 16 to 17 of WO '101). If the dissolution of bioactive porous silicon was extensive it would prevent bond formation with tissue, which is a characteristic of bioactive materials (page 1, lines 10 to 12 of WO '101).

The terms "resorbed" and "eroded" refer to the same event, namely the dissolution of the silicon (paragraph spanning pages 27 and 28 of the present application).

In summarizing applicants' arguments (on page 3, last paragraph, 4th sentence) the Office Action states: "WO '101 would lead the skilled person away from use of resorbable mesoporous silicon for drug delivery. Applicant's argue this is because mesoporous silicon would corrode". This statement may not have taken complete account of the following facts set out in WO '101:

(a) microporous silicon is associated with bioactivity (page 13, line 28);

(b) the impregnation of calcium is associated with apatite growth and hence bioactivity (page 14, lines 1 to 2 and page 3, lines 8 to 10);

(c) the main uses of bioactive silicon, described in WO '101, are: as a material suitable for forming a bond with bone or tissue (p3 l 3-5, p 6 l 2-3, p15 l 24-26, p 22 l 13-14) and as an implant packaging material (p 2 l 25-29, p 3 l 5-6, p 6 l 2-3, p 22 l 15-16).

These extracts from WO '101 show that calcium chloride impregnated porous silicon, highlighted by the examiner, is strongly linked to packaging and bone-bonding applications that are inconsistent with resorption. This would therefore lead the skilled person away from the substitution of bioactive microporous silicon with resorbable mesoporous silicon, and it follows that claim 144 is non-obvious.

WO '101 does not disclose microporous silicon of a range of pore sizes less than 20 A silicon combined with a drug (i.e. there is no generic disclosure). It describes a specific form of microporous silicon combined with calcium chloride. The specific form is fabricated by anodization of a 30 ohm/cm CZ silicon wafer at 20 $mAcm^{-2}$ for one minute in 40% aqueous HF.

In order to show "obviousness", the Examiner must explain why it would be obvious to make such a substitution. In asserting that "it would be obvious ... to use the silicon because it erodes", no explanation is provided, hence the rejection appears to be based upon conjecture.

A consideration of the following facts also points to the patentability of applicants' claims:

(a) 33 of the 45 PCT published claims refer to bioactive silicon;

(b) 39 of the claims relate to bioactive silicon or silicon and a mineral deposit;

(c) microporous silicon is associated with bioactivity (page 13, lines 25 to 28);

(d) there is a link between bioactivity and tissue compatibility (page 16, lines 29 to 34);

(e) there is nothing in WO '101 to suggest that resorbable mesoporous silicon would be bioactive or tissue compatible; and

(f) drug delivery is only mentioned in connection with bioactive silicon (page 6, lines 5 to 6 and page 16, lines 5 to 6).

These facts show that WO '101 places great emphasis upon the use of bioactive silicon, which is associated with tissue compatibility. An objective addressed by the present invention is the provision of a tissue compatible implant. Therefore this would lead the skilled person towards a microporous bioactive silicon implant and away from the use of mesoporous resorbable silicon.

Applicants believe there is a clear link between microporous silicon and drug delivery, given in WO '101, and no link between mesoporous silicon and drug delivery. It would therefore not be obvious to use silicon in the mesoporous range of pore sizes.

The narrow line between the two pore ranges is also not relevant in this case, since WO '101 is concerned with a specific form of microporous silicon that is combined with calcium chloride. No mention is made of microporous silicon, having a range of pore sizes, combined with a drug.

It appears to be the examiner's position one skilled in the art would view WO '101 as the use of resorbable mesoporous silicon would be desirable when developing a controlled drug release implant. In fact, such an approach would amount to a modification of the overall teachings of WO '101, for the reasons explained in detail above.

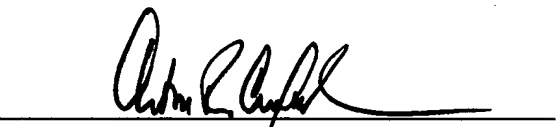
The U.S. Court of Appeals for the Federal Circuit has stated that "[t]he mere fact that the prior art may be modified in the manner suggested by the examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992) (citing *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)).

It is clear the reference teaches the opposite of that which the examiner insists is a tailoring of the resorption profile.

For the above reasons it is respectfully submitted that claims 144-153 define patentable subject matter. Reconsideration and allowance are solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

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